REMARKS

Claims 1, 2 and 4-7 are currently pending. Claim 1 has been amended. Support for the amendment can be found in the specification at page 5, lines 8-11 and page 6, lines 3-7. Claims 2 and 4 have been amended to further clarify what is being claimed. Because the foregoing changes introduce no new matter, their entry is respectfully requested.

Rejection under U.S.C § 101

Claims 1, 2 & 4-7 stand rejected under 35 U.S.C § 101 for lacking utility. The Examiner asserts that "the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility." Applicants respectfully traverse.

The claimed invention satisfies the specific utility requirement

The Examiner, citing a passage on page 32 of the specification (quoted on page 3 of Office Action, Paper 43), suggests that "DRG11 is not a 'specific' marker..., but a 'general' marker 'similar to that of SCG10...or Isl-1' which therefore refers to a general class of compounds." Applicants respectfully point out that the passage has been taken out of context.

The passage to which the Examiner cites is in reference to an in situ hybridization study conducted to determine whether DRG11 expression was restricted to a specific subset of sensory neurons (i.e., only sensory neurons that project to the dorsal spinal cord). The data demonstrates that DRG11 can be expressed in sensory neurons, other than the ones that project to the dorsal spinal cord. SCG10 and Isl-1 are markers that label *all* sensory ganglia and are, therefore, expected to be present in the sensory neuron samples. This data, however, does not contradict Applicants' assertion that DRG11 can be used to distinguish sensory neurons and dorsal horn

neurons of the spinal cord from non-neuronal cells, sympathetic neurons, and ventricular neurons of the spinal cord.

Section 2107.01 of the MPEP defines "specific utility" as a utility that is "*specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention." Utility is considered general "where an applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful.

The present invention meets the specific utility requirement. DRG11 is specifically expressed in mammalian sensory neurons and not expressed in autonomic neurons or glia. *See* Specification, page 20, lines 3-4. This differential expression of DRG11 can be exploited for the detection of the presence or absence of sensory neurons or to identify neurons in the peripheral sensory lineage. *Id.* at page 2, lines 16-17. Thus, the ability to use DRG11 to identify sensory neurons constitutes a specific utility.

The claimed invention satisfies the substantial utility requirement

The Examiner also states that the claimed invention lacks substantial utility because "basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved does not define 'substantial utility...'"

The standard for assessing substantial utility is "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient." M.P.E.P. § 2107.01. Applicants have identified reasonable uses: to provide a marker to identify neurons in the peripheral sensory lineage, as well as, to detect the presence or absence of sensory neurons. *See* Specification at page 2, lines 16-17 and page 20, lines 1-8.

Contrary to the Examiner's assertion, the claimed invention does have a real world context of use. It is known in the art that transcription factors can serve as useful markers of

neuronal identity. *Id.* at page 1, line 9. The present invention discloses that DRG11 is a sensory neuron-specific transcription factor. *Id.* at page 28, lines 14-16. Thus, one skilled in the art would find "real world" utility in being able to differentiate between sensory and non-sensory neurons during neurogenesis. Furthermore, the utility of a marker for cells destined to be peripheral sensory neurons is substantial and well established. Such markers can be used to obtain or isolate pools of such neurons. The skilled artisan will readily see the utility of such a marker in isolating peripheral sensory neurons for investigation of neurodegenerative diseases or neural injury, to name but two examples.

The invention does not just simply study the properties of DRG11 or the mechanisms in which DRG11 is involved. Rather, the present invention describes the discovery of DRG11 and its specific expression in sensory neurons and dorsal horn neurons of the spinal cord. The selective expression of DRG11 allows the skilled artisan to use DRG11 to identify sensory neurons to the exclusion of sympathetic neurons.

The Examiner also indicates that the present invention fails the substantial utility requirement because the specification does not adequately describe an assayable function for DRG11. According to the Examiner, this indicates that Applicants have not conveyed with reasonable clarity to those skilled in the art, as of the filing date sought, that Applicant was in possession of the claimed invention.

The Examiner's attention is directed to the in situ hybridization experiments and monoclonal antibody screening in the specification (page 30, line 4 to page 34 line 17), where the data show that DRG11 is a sensory neuron-specific marker. The specification describes the method of isolating DRG11 and the ability to detect DRG11 in sensory neurons specifically. The skilled artisan would immediately recognize the utility of identifying peripheral sensory neurons.

Accordingly, Applicants submit that the present invention as disclosed in the claims has a specific and a substantial utility and respectfully request that the Lack of Utility rejection under 35 U.S.C. § 101 be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-2 and 4-7 also stand rejected under 35 U.S.C. § 112, first paragraph. According to the Examiner since the claimed invention is not supported by either a specific and/or substantial asserted utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully request that the Examiner consider the arguments made in the above section regarding utility. As discussed above, the cited claims do satisfy the utility requirements. Thus, Applicants request the withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1 and 5-7 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that one of ordinary skill in the art cannot reasonably visualize what generic nucleic acid sequences are specifically encompassed by these claims.

Applicants have amended claim 1 to recite a nucleic acid encoding a DRG11 protein that is at least 90% identical to SEQ ID NO: 2 wherein said DRG11 protein has a homeodomain region which is at least 95% identical to the homeodomain region comprising amino acid residues 30 through 90 of SEQ ID NO: 2. In addition, said DRG11 protein is characterized by its natural expression in sensory neurons and dorsal horn neurons of the spinal cord and non-expression in non-neuronal cells, sympathetic neurons and ventricular neurons of the spinal cord.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction practice, reduction to drawings, or by disclosure of relevant identifying characteristics, (*e.g.*, structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. *See* M.P.E.P. § 2163 (II)(A)(3)(a)(ii).

The specification contains a written description which supports amended claim 1. The specification provides the amino acid sequence (*i.e.*, SEQ ID NO: 2) and discloses that the protein is a transcription factor that has a specific expression pattern. The claimed nucleic acids of claim 1 require a DRG11 protein that is: (1) 90% homologous to SEQ ID NO: 2 overall, (2) 95% identity to the homeodomain region comprising amino acid residues 30 through 90 of SEQ ID NO: 2, and (3) is expressed in sensory neurons and dorsal horn neurons of the spinal cord and not expressed in non-neuronal cells, sympathetic neurons and ventricular neurons of the spinal cord. These limitations define a set of nucleic acids which satisfy the written description requirement by including structural and functional characteristics of the protein encoded by the claimed nucleic acids.

The Examiner directs Applicants to Example 11 in the Revised Interim Written Description and Utility Guidelines. Sample claim 1of Example 11 is recites "an isolated DNA that encodes Protein X (SEQ ID NO: 2)." In the analysis, sample claim 1 is determined to be allowable even though "only one specie within the genus is disclosed, SEQ ID NO: 1, a person of

skill in the art could readily envision all the DNAs degenerate to SEQ ID NO: 1 by using a genetic code table."

Applicants submit that claim 1 of the instant invention is similar to the allowable sample claim 1 in Example 11. Specifically, both claim a nucleic acid that encodes a protein. The instant invention claims a nucleic acid encoding a DRG11 protein that is at least 90% identical to SEQ ID NO: 2 wherein said DRG11 protein is at least 95% identical to the homeodomain region comprising amino acid residues 30 through 90 of SEQ ID NO: 2. Similarly, sample claim 1 of Example 11 claims an isolated DNA that encodes protein X. Thus, Example 11 of the Guidelines supports Applicants' position that the claims of the instant invention meet the written description requirement.

The Examiner also cites *Fiers v. Revel*, *Fiddes v. Baird*, and *University of California v. Eli Lilly* for the proposition that the skilled artisan could not reasonably visualize what constitutes generic sequences encompassed by claims that are based solely on the written description of the single cDNA sequence of SEQ ID NO: 1. Applicants submit that the cited cases are inapposite to the present application.

In *Fiers*, Fiers did not disclose *any* sequence, yet Fiers asserted a date of invention of the β-IF gene based only upon disclosure of a method for isolating the gene. *See* Fiers v. Revel, 25 USPQ2d 1601, 1604 (Fed. Cir. 1993). The court rejected Fiers' argument that conception may be established through merely "defining its hoped for function." *Id.* at 1605. In contrast, Applicants have disclosed the sequence of the DRG11 protein (SEQ ID NO: 2), as well as, the

manner in which a DRG11 nucleic acid can encode the DRG11 protein. *See* specification, page 5, lines 8-22 or page 7, lines 4-12.

The *Fiddes* case cited by the Examiner is also distinguishable. In *Fiddes*, the application claimed a broad class of mammalian FGFs. Baird sought the earlier filing date of a patent application that had issued in a related case. Baird's original patent disclosed an amino acid sequence and a theoretical DNA sequence for bovine pituitary FGF, but did not provide a written description of the naturally-occurring gene sequence encoding mammalian FGF. *See* Fiddes v. Baird, 30 USPQ2d 1481, 1483 (Bd. Pat. App. & Int'f. 1993). As a result, the board held that the patent did not provide sufficient written description to support the claims to the nucleic acids encoding FGF.

By contrast, Applicants have disclosed both the amino acid sequence and the nucleotide sequence of DRG11. In addition, other identifying characteristics of DRG11, as mentioned above, serve to sufficiently describe the members of the genus that would define a particular sequence as encoding a DRG11 protein.

The Examiner cites *University of California v. Eli Lilly*, 43 USPQ2d 1398(Fed. Cir. 1997), for the proposition that "[t]he exemplification of a single sequence...does not constitute a description of [a] genus." Applicants submit that this reference is not applicable to the present case. In the cited reference, the issue was whether a claim to "mammalian insulin cDNA" was available from a disclosure of only one rat cDNA sequence. The court was concerned that the generic description was based only on function and did not define common structural features. That is quite different from the present case, wherein the claims are drawn to nucleic acids encoding a protein which is 90-95% identical to a fully disclosed DRG11 protein sequence.

Moreover, the claims, as amended, describe the properties of the proteins encoded by the claimed nucleic acid sequences. The facts of this case, as distinguished from *Lilly*, provide a common structural basis for the claimed sequences.

Accordingly, one of ordinary skill in the art would, thus, conclude that Applicants were in possession of the claimed nucleic acid sequences at the time of filing this application. Applicants respectfully request withdrawal of the rejection of the claims 1 and 5-7 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

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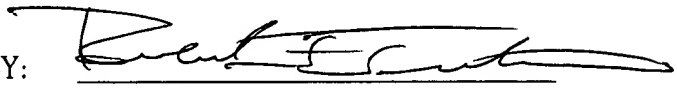
BY: 

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